Calcium Stearate
Processing

Executive Summary[1]

A petition is under consideration with respect to NOP regulations subpart G §205.605, governing the use of substances in processed products:

Petitioned: **Inclusion of calcium stearate on National List of nonagricultural substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."**

Calcium stearate is a compound of calcium with a mixture of solid organic acids obtained from edible sources. It is generally used as a solid-phase lubricant that reduces friction between particles of the substance to which it is added. The Petitioner's intended use is "as a flow agent (anti-dusting agent)" to be used in dry flour based ingredients sold to bakeries (NOSB Petition). The NOP has no prior listing or ruling on the substance.

All three reviewers agreed that the substance should be considered synthetic. The reviewers were divided over the use of calcium stearate in food labeled as "organic." Two of the reviewers felt it should not be allowed in these foods, while one reviewer felt it should be accepted. One reviewer who voted to restrict its use indicated that more information was needed on the nature of the substance and its potential applications, and the other reviewer felt that inclusion of a "synthetic" substance in organics runs contrary to consumer's expectations regarding organic products. All three reviewers agreed that the substance should be allowed in products labeled as "made with organic…" ingredients. One reviewer felt that these products should be accompanied by a label that states the potential animal sourcing of calcium stearate.

Summary of TAP Reviewer Analyses

Products considered "organic" (>95%)

Synthetic/ Nonsynthetic	Allowed or Prohibited	Notes/suggested annotations:
Synthetic (3) *Nonsynthetic (0)*	*Allowed (1)* *Prohibited (2)*	***Reviewer 1:*** *Prohibited, no annotation.* ***Reveiwer 2:*** *Allowed, no annotation* ***Reviewer 3:*** *Prohibited, no annotation*

Products considered "made with organic (specified ingredients or food group(s))" (>70%)

Synthetic/ Nonsynthetic	Allowed or Prohibited	Notes/suggested annotations:
Synthetic (3) *Nonsynthetic (0)*	*Allowed (3)* *Prohibited (0)*	***Reviewer 1:*** *Allowed, no annotation* ***Reveiwer 2:*** *Allowed, no annotation* ***Reviewer 3:*** *Allowed, provided that its use and its potential animal sourcing are stated on the label.*

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the contractor's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and evaluation presented to the NOSB is based on the technical evaluation against those criteria, and does not incorporate commercial availability, socio-economic impact or others factors that the NOSB and the USDA may consider in making decisions.*

Identification

Chemical name: calcium stearate
Other names: stearic acid calcium salt, octadecanoic acid calcium salt
CAS Number: 1592-23-0
International Numbering System for Food Additives: Not listed
Other: None found.

Characterization

Composition:
$Ca(C_{18}H_{35}O_2)_2$

Physical Data:

Molecular wt.:	607.03
Melting point:	179°C
Specific gravity:	1.04
Solubility:	Practically insoluble in water (0.04g/L H_2O @ 15°C), ether, chloroform, acetone, and cold alcohol Slightly soluble in hot alcohol, hot vegetable and mineral oils Quite soluble in hot pyridine
Stability:	Stable under ordinary conditions of use and storage
Hazardous polymerization:	Will not occur

Properties:
Calcium stearate is a metallic, water soluble stearate. It is a compound of calcium with a mixture of solid organic acids obtained from edible sources, and consists chiefly of variable proportions of calcium stearate and calcium palmitate (NAS 1996). It occurs as a fine, white to yellowish white, bulky powder having a slight, characteristic fatty odor.

Action:
Calcium stearate is a solid-phase lubricant that reduces friction between particles of the substance to which it is added. It functions by complexing with protein and starch (Kamel 1993).

How Made:
Traditionally, calcium stearate was made by reacting calcium chloride, sodium stearate, and other salts of mixed fatty acids in an aqueous solution, then isolating the precipitate (Kebrich and Petrot 1953). According to the Petitioner, this method is not practical for large-scale production, and instead the substance is derived from a dry fusion process in which palm-derived stearic acid is reacted with calcium oxide; no organic solvents are used in this process. Stearic acid is a naturally occurring saturated fatty acid present in the glycerides of animal fats and most vegetable oils, and is derived from palm oil, soybean oil, or edible tallow. The finished product is composed of calcium with variable proportions of stearic and palmitic acids, and contains the equivalent of 9-10.5% calcium oxide (Osol and Hoover 1975). It is available in powder, ground, or beaded form and is made from stearic acid of 50-90% composition (Kamel 1993). Calcium stearate is available in technical and food grades (Hawley 1977).

Uses:
Extremely low solubility makes calcium stearate a very versatile substance. It is mainly used as a dough conditioner and is commonly used with other dough softeners such as mono- and diglycerides (Kamel 1993). Food grade calcium stearate can also be used as an emulsifier, flavoring agent, anti-dusting agent, stabilizer, release agent, and/or thickening agent (Merck 2001). Other uses include waterproofing, as a releasing agent for plastic molding powders, as a stabilizer for polyvinyl chloride resins, lubricant, and as a conditioning agent in various pharmaceutical products (Merck 2001).

Table 2. Sample Levels of Industry Additions of Calcium Stearate to Foods by Category

Food category	Weighted mean %
Baked goods, baking mixes	1.03
Fats and oils	0.06
Meat products	0.02
Poultry products	0.02
Eggs, egg products	0.02
Fish products	0.02
Soft candy	0.92
Soups, soup mixes	0.02
Snack foods	0.02
Gravies, sauces	0.03
Hard candy	0.08
Seasoning and flavors	0.64

NAS 1972

Status

History of Use:
Calcium stearate was first isolated for commercial use in 1924 (Harrison). Its use as a bread dough strengthener/crumb softener was identified by Dubois (1979). Its physical qualities and low toxicity make it a versatile additive in a wide range of products, some of which are listed in Table 2.

Functionality

Calcium stearate is a nonagricultural product. It is virtually nontoxic, and its unctuous properties make it ideal for use in food products (Osol and Hoover, 1975). Commercially it is used in flour enrichment and dough conditioning products marketed to bakeries. The Petitioner's intended use is "as a flow agent (anti-dusting agent) to be used in flour enrichments which are added at flour mills, and also to be used as a flow agent or anti-dusting agent in dry flour-based ingredients containing enzymes which may be either added at the flour mill or at the bakery (dough improvers)" (NOSB Petition addendum). In this way, calcium stearate improves the manageability of dough and minimizes airborne bakery dust. According to the Petitioner, this is important for bakery workers who may experience harmful effects from inhalation of bakery ingredient dust. Some flour conditioners contain potentially allergenic enzymes, and dust from certain vitamins (e.g. thiamin, a vasodilator) can be harmful (NOSB Petition).

USDA Final Rule

The USDA has no prior ruling on the use/prohibition of calcium stearate, and currently there are no references to the substance in NOP regulations. NOP parameters specifically relating to the Petitioner's request are as follows:

> **§ 205.301 Product Composition.**
>
> (b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part.[α] If labeled as organically produced, such product must be labeled pursuant to § 205.303.
>
> (c) Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))." Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (1), (2), and (3) of § 205.301(f). Nonorganic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

Regulatory:

Domestic certifiers: The OTA American Organic Standards defers to processing substances allowed by the NOP National List (§ 7.4.3.6). All Northeast Organic Farming Association (NOFA) chapters (MA, CT, NJ, NY, VT, RI) are in the advance stages of transitioning to the NOP National List, and none of them have a prior ruling on the use of calcium stearate.

International certifiers: The UN/FAO Codex Alimentarius does not regulate calcium stearate, but it has registered several substances that are chemically and functionally similar (calcium stearoyl lactylate, calcium stearoyl-2-lactylate, calcium stearoyl lactate) under the Joint FAO/WHO Expert Committee on Food Additives (JECFA). IFOAM does not include calcium stearate on its List of Approved Additives and Processing Aids. Japanese Agricultural Standards have no ruling on the use of calcium stearate.

FDA regulates calcium stearate under Title 21of the Code of Federal Regulations (CFR). Table 1 summarizes these references. In addition, regulations require that fatty acids and oils used in production of stearic acids must be free of chick edema factor (Rossoff 1974).

EPA List of Inert Pesticide Ingredients (2001) classifies calcium stearate on List 4B (Inerts which have insufficient data to substantiate they can be used safely in pesticide products).

NIEHS National Toxicity Program (NTP) Database does not list any regulatory limits for calcium stearate (NTP 2002).

OSHA classifies the substance as hazardous under the criteria of the Hazard Communication Standard 29 CFR 1910.1200.

International Agency for Research on Cancer (IARC) does not regulate the substance as a carcinogen.

[α] *Author's note:* Evaluation criteria for inclusion on National List are given below.

Table 1. FDA References to Calcium Stearate		
21 CFR	**Section Heading**	**Annotation**
169.179	Vanilla powder	Optional adjuvant for use as an anticaking ingredient in vanilla powder mixtures, not to exceed two percent of powder mixture by weight.
172.863	Salts of fatty acids	Lists parameters for use of salts of fatty acids in food components, including mixture composition and labeling of additives.
173.340	Defoaming agent	Optional adjuvant for use as a defoaming agent in processing beet sugar and yeast.
175.300	Resinous and polymeric coatings	Miscellaneous ingredient permitted for use in coating of food-contact surfaces of materials used in any aspect of processing or packing.
177.2410	Phenolic resins in molded articles	Optional adjuvant employed in the production of phenolic resins to confer lubricant qualities.
177.2600	Rubber articles intended for repeated use	Optional adjuvant for use as a plasticizer, not to exceed thirty percent of rubber product by weight.
178.1010	Sanitizing solutions	Optional adjuvant for preparation of sanitizing solution described in detail at (b)(41), not to exceed eight percent of preparation.
179.45	Packaging materials for use during the irradiation of prepackaged foods	Optional adjuvant for use in polyethylene film, not to exceed one percent of the polymer by weight, prepared from basic polymer described in 21CFR177.1520(a), and subjected to irradiation dose described in (10)(c).
178.2010	Antioxidants and/or stabilizers for polymers	Optional adjuvant for use as anitoxidant/stabilizer in polymers used in articles intended for use in all aspects of food processing and packing.
181.29	Stabilizers	Classified as stabilizer, when migrating from food packaging material.
184.1229	Calcium stearate	GRAS when used in accordance with GMPs.

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. ***The potential of substance for detrimental chemical interactions with other materials used in organic farming systems.***
   The intended use of the substance as a processing material precludes it from interacting directly with other materials used in organic farming.

2. ***The toxicity and mode of action of the substance, its breakdown products or contaminants, and their persistence and areas of concentration in the environment.***
   Calcium stearate is considered to be nontoxic (GRAS) when used in accordance with GMPs (FASEB 1975, ACT 1982). No research was found regarding breakdown products, contaminants, or toxic interactions in the environment.

3. ***The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.***
   See processing Criteria 2, below.

4. ***The effect of the substance on human health***
   See Processing Criteria 3, below.

5. ***The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms, crop, and livestock.***
   The Petition is for use as a processing material and thus are not applicable apply to agroecosystem interactions.

6. ***The alternatives to using the substance in terms of practices or other available materials.***
   See Processing Criteria 1 and 7, below.

7. ***Its compatibility with a system of organic agriculture.***
   See Processing Criteria 6, below.

Processing Criteria from the February 10, 1999 NOSB Meeting

1. ***The processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes***

No documentation was found referring to natural sources of food grade calcium stearate. Lecithin shares similar emulsification properties with calcium stearate, but may not be as versatile. Lecithin is a versatile surfactant composed primarily of phospholipids. Similar to calcium stearate, it is available as a course or fine powder and can be used in food products as a dough conditioner, emulsifier, or release agent. It also has the benefit of current approval on the National List (§205.606). No references were found that characterized lecithin as an anti-dusting agent – the petitioner's primary intended purpose of calcium stearate –and its effectiveness in this regard is not established.

2. Manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA

As stated above, calcium stearate is a nonagricultural product, and specific information on the modern manufacturing process is proprietary business information and is not available. The process involves a reaction of calcium oxide or calcium hydroxide and stearic acid (see "How Made", above). The Petitioner does not manufacture calcium stearate, but purchases it from another source. This source uses a confidential "non-aqueous fusion" process. No sources were found giving detailed information on this process. In response to an initial version of the TAP Review, the petitioner supplied SAREP with non-detailed manufacturing information from another supplier stating that "stearic acid reacts readily with many chemically basic metal reactants when given the proper temperature, catalysis, and mechanical energy input" (Petition addendum).

To the best of the investigator's knowledge, calcium stearate has not been evaluated for its effects on the environment. Similarly, there is limited toxicity research on stearic acid, focusing mostly on toxicity effects in food and cosmetic ingredients (ACT 1982). Based on its low acute toxicity, it would likely present a low risk to the environment if spilled.

Calcium stearate is mixed with dry flour based blends sold to bakeries. Breads and bakery goods are common organic products, and the Petitioner's intended use as a dry blend additive appears to be consistent with GMPs as they pertain to organic processing.

3. The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations

The only thorough toxicological evaluation of calcium stearate was conducted for its use in cosmetics (ACT 1982). The substance was tested with ten other metallic stearates for toxicity effects. Acute oral studies with rats indicated that the stearates are "practically nontoxic, and have low potential for acute dermal toxicity." Dermal irritation studies with rabbits showed that stearates are "only minimal to slight irritants at high concentrations."

Acute Toxicity (Dugan 1996):

Inhalation:	May irritate respiratory tract. Symptoms may include coughing, shortness of breath, sore throat and runny nose. Avoid breathing dust. Use local ventilation if dusting is a problem. Provide respiratory assistance as needed.
Ingestion:	May cause gastroenteritis, with abdominal pain, nausea, vomiting and diarrhea. Systemic effects may follow and may include ringing of the ears, dizziness, elevated blood pressure, blurred vision and tremors. If ingested, call a physician immediately.
Skin contact:	May cause irritation with symptoms of redness, swelling, itching and pain. Flush with water, wash clothing before reuse.
Eye contact:	May cause irritation with symptoms of redness, swelling, itching, tearing and pain. Flush with water for at least 15 minutes.

Calcium stearate is used in food in relatively small quantities (see Table 2, above), and the substance has not been shown to impact nutritional quality when used in accordance with GMPs (FASEB 1975). Calcium stearate is considered non-toxic (ACT 1982). To the best of the investigator's knowledge, the chemical, physical, and toxicological properties of calcium stearate have not been thoroughly examined. Stearic acid, the primary metabolite of calcium stearate, has the following toxicological properties:

LD_{50}=	21,500µg/kg (IV, rat)
LD_{50}=	23 mg/kg (IV, mice)
LD_{50}=	>5 g/kg (dermal, rabbit)
Dermal irritation	Mild in humans following 75mg application over three days. Moderate in rabbits at 550mg/24hr.

Several short term studies of stearic acid and animal tallow were performed that evaluated their health aspects as food ingredients. Day old chicks fed 5 percent stearic acid for 4 weeks exhibited no deleterious effects (Deichmann *et. al* 1958). Anorexia, constipation, and listlessness and fever were observed in dogs given a diet of 5 percent stearic acid (Wikoff *et. al* 1947). Rats kept on a diet of 0.3% stearic acid for 209 days did not develop gross or microscopic pathological lesions (Deichmann *et. al* 1958). The addition of corn oil to the diet of rats being fed high amounts of stearic acid markedly reduced mortality rates (Price *et. al* 1960). Stearic acid is considered non-carcinogenic in tests with mice (Van Duuren *et. al* 1972).

In humans, digested fat glycerides are separated in the intestine and free fatty acids are absorbed through the intestinal wall. When labeled stearic acid is fed to rats, labeled carbon is found in the palmitic and oleic acid fractions of stomach bile (White *et. al* 1973). Tallow appears to be easily absorbed in livestock. Absorption of tallow in animal feed by chicks at eight weeks was the same as adult hens (Renner & Hill 1960). In calves, the digestibility of tallow was 87.6 percent when fed at a level of 5 percent in an all-concentrate diet (Raven 1969). In contrast, the digestibility of stearic acid appears to be

quite low. Stearic acid fed to adult rats as a mixture of calcium stearate and the free acid was less digestible than when fed the free acid in semi-synthetic rations (Cheng *et. al* 1949). Low digestibility of stearic acid was initially identified as a concern in the 1950s due to its potential links to cholesterol formation (Keys *et. al* 1957, 1965). There is some evidence that stearic acid is strongly thrombogenic (i.e., tending to attract clotting) when fed to rats at a rate of three to six percent (Renaud 1969). More recent studies in humans and animals suggest that ingestion of stearic acid has a neutral or cholesterol-lowering effect in contrast to lauric, myristic and palmitic acids (Monsma and Ney 1993).

Humans commonly consume stearic acid as a glyceride component of fats in meat and table spreads. Concentrations in food range from 0.02% to 1%. In terms of actual intake, stearic acid supplies approximately 3-4% of the total calories in the U.S. diet (Pearson 1993; Kris-Etherton *et. al* 1993), with cocoa butter (typically consumed as chocolate) contributing proportionally the most stearic acid of commercially available fats. A survey of the food industry by a National Research Council subcommittee estimated 26,198kg of stearic acid were used by the food industry in 1970 (NAS 1972). Based on the numbers put forth in that report, estimates of intake of stearic acid are 0.35mg per capita daily.

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law

Registered uses of calcium stearate in food products are listed Title 21 CFR and are summarized in Table 1, above. The Petitioner's primary intended use is to minimize airborne dust, which can pose a health hazard for bakery workers. According to the petition, the substance is used "as a flow (anti-dusting) agent to be used in flour enrichments added at flour mills and… in dry flour-based ingredients containing enzymes which may either be added at the flour mill or at the bakery." The Petitioner markets additives that contain vitamins such as niacin and thiamin, which act as vasodilators and can cause adverse side effects if inhaled in sufficient quantities (NOSB Petition).

Potential hazards of airborne bakery dust are a proven concern. Musk and Venables (1989) established a link between bakery dust and allergenic respiratory responses. In one study in the UK, flour/grain dust accounted for 8% of work related respiratory illnesses, with bakers ranking third among occupational groups in terms of increased asthma incidence (Meredith *et. al* 1989). Calcium stearate is also used to reduce airborne dust particles in some mining operations for similar health and safety concerns (EPA 1994).

Calcium stearate does not appear to act as a preservative or add significant nutritional value to the products to which it is added (FASEB 1975). However, the substance is added to products that the Petitioner describes as "vitamin enrichments" and "dough improver products". The former may fall under the category of a substance that is used to recreate/improve nutritive value. Thus, the approval of calcium stearate may aid in the marketing of food additives and preservatives as certified organic.

5. It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances

Calcium stearate is considered GRAS as a multiple purpose ingredient with no use limitation other than current GMP (21 CFR 184.1229). It contains no heavy metal residues or other contaminants regulated by the FDA.

6. Its use is compatible with the principles of organic handling.

The NOP has no prior position on the use of calcium stearate. The substance is blended into various dry blends, which are then sold to bakeries. This use does not incorporate processing methods "that compromise the integrity and quality of finished products," a principle of organic handling proposed by the NOSB.

As stated above, the primary use of the substance is as a flow/anti-dusting agent to be used in flour enrichments added at mills and bakeries to reduce airborne dust. Calcium stearate also has a significant number of additional food uses based on its functionality as an emulsifier, surfactant, stabilizer, and release agent. A cursory internet search yielded extensive references regarding the use of calcium stearate in pharmaceuticals, dietary supplements, and processed food packaging. Since a non-annotated approval of calcium stearate to the National List would effectively allow uses beyond the scope of the petitioner's intended use, the compatibility of other processing methods with organic standards remains in question.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

Calcium stearate is commonly used in the US at the level of 0.5% of flour weight (Kamel 1993). According to the Petitioner, their calcium stearate-enriched products "contain no more than 1% calcium stearate by weight. The actual enrichment product is added to the flour at the mill at ¼ ounce per hundredweight." At a maximum, this translates in to additions of $1/100^{th}$ of 156ppm to the flour (NOSB Petition).

There are numerous mono- and diglycerides used in bakery blends that act as crumb softeners/dough strengtheners and surfactants (AIB 1979). Lecithin is noted in this report as conferring similar dough conditioning properties as calcium stearate, and in addition it has current approval on the National List. Like calcium stearate, lecithin is used in baking

products at approximately 1% dry weight, and is marketed as dough conditioner, release agent, and emulsifier. Despite its functional similarity, its use specifically as an "anti-dusting" agent has not been demonstrated and so its efficacy in this regard is not established.

TAP Reviewer Discussion

Reviewer 1 *[Ph.D., Agricultural & Environmental Chemistry; extension food toxicologist, emphasizing in naturally-occurring food toxins, western US]*

NOSB Processing Criteria Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes*
   The "How Made" discussion indicates that calcium stearate is synthesized from a reaction of calcium chloride, sodium stearate, and other salts of mixed fatty acids. All of these precursors for calcium stearate appear to be available from natural sources although their actual origins in the specific synthesis of calcium stearate are unknown. Interestingly, sodium stearate can be obtained from natural sources and may have its own use as a flow agent based upon its structural similarity to calcium stearate. As for other organic ingredients that could be used as substitutes, the UC SAREP review mentions lecithin as a potential substitute. Magnesium stearate has also been listed as a potential flow agent. While these substances may not achieve the specific efficacy as flow agents that calcium stearate could achieve, it is clear that organically-allowed substitutes are available.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*
   Calcium stearate does not appear to pose environmental concerns.

3. *The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
   I concur that the small amounts of calcium stearate should not have any significant impact upon the nutritional quality of the food in the amounts in which it is considered for use.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
   The draft review document lists several additional food additive functionalities of calcium stearate beyond its use as a flow agent, including emulsifier, anticaking agent, flavoring agent, stabilizer, release agent, and thickening agent. The *Food Additives Handbook* (page 114) also lists properties of binder and release agent for calcium stearate. While it seems clear that its *primary* use is as a flow agent, its properties as a flavoring agent should at least be considered when making the determination as to its applicability under NOSB criteria.

5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
   Calcium stearate, when used in the proposed manner, is essentially innocuous and therefore presents no toxicological concern. Its manufacturing process should not result in heavy metal residues or other contaminants as it is produced and isolated as a non-water soluble precipitate.

6. *Its use is compatible with the principles of organic handling.*
   The use of calcium stearate as a flow agent for baking should not compromise the principles of organic handling.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
   As discussed previously, sodium stearate is a naturally-occurring precursor for the synthetic production of calcium stearate and possesses its own flow agent properties. At least two other NOSB-approved substances also have been listed as flow agents.

[The Reviewer did not reply directly to questions regarding additional references, substitutes, and alternative manufacturing processes]

Recommendations to the NOSB:

a) Calcium stearate should be considered **synthetic** based upon its method of production.
b) Calcium stearate should be **prohibited in processed products labeled "organic"** on the basis of its chemical similarity to magnesium stearate which is prohibited in agricultural products labeled "organic."
c) Calcium stearate should be **allowed for use in processed products labeled as "made with organic (specified ingredients or food group(s))"** on the basis of its chemical similarity to magnesium stearate which is allowed in agricultural products labeled as "made with organic (specified ingredients or food group(s))."

Reviewer 2 *[Ph.D., Physical Chemistry, focus on grain science; specializing in colloids and interfacial chemistry; relationships between grain composition and functionality; application of this knowledge to manipulation of grain/flour properties in processing and breeding; Midwestern US]*

NOSB Processing Criteria Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes*
   Calcium stearate is a synthetic product and cannot be produced from a natural source. Its formula consists of one calcium atom attached covalently to two stearic acid chains. As far as I know, calcium stearate does not occur naturally although its main ingredient (stearic acid) can be derived from natural sources, animal and vegetable fat. Stearic acid is the main component obtained from natural fats with other fatty acids, principally palmitic acid, present in small amounts. As a result, the product sold as calcium stearate will contain a small amount of palmitic acid chains. Several methods are available for synthesizing calcium stearate. The one used by the supplier of the petition is the most acceptable environmentally.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA*
   Calcium stearate is manufactured by a dry fusion process and does not involve organic solvents. Based on the evidence, its use and disposal do not have any adverse effects on the environment.

3. *The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations*
   The nutritional quality of the food is not affected and the material and any breakdown products would not have adverse effects on human health, certainly at the levels intended.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law*
   Its primary purpose is to reduce dust levels from flour. This may not have been made clear in the main petition where the more technical term "free-flowing agent" is used. However, it seems to have been clarified in the response to points made by the UC SAREP. Its purpose is to reduce the amount of dust from flour and this is particularly important to the petitioners as they are supplying enrichment products which may contain enzymes and vitamins. Some of these compounds can be harmful if inhaled. Hence they are justified in being concerned about these effects. It is not to be used as a preservative or used only to recreate or improve flavors, colors, textures or nutritive value lost during processing.

5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
   It is Generally Recognized as Safe (GRAS) by FDA. I am not aware of any reason to question this.

6. *Its use is compatible with the principles of organic handling.*
   As far as I can surmise, its use is compatible with the principles of organic handling. A product is represented as "organic" if it contains not less than 95% organically produced product. The intended use of calcium stearate in flour is at an addition of the order of 150 parts per million or 0.015% flour weight. At this concentration, it should be allowed for use in flour without affecting labeling of the flour as "organic".

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process*
   It is used in a very small amount which possibly is the minimum quantity required to achieve its purpose, although no evidence is provided with respect to this. In regard to similar products with the same effect, the one suggested, lecithin (phosphatidyl choline), is present in wheat flour. The lipid content of wheat flour is usually 1-2% by weight. About one fourth of this occurs within the starch granules and therefore should not exert an effect on flow properties. The non-starch lipid is a complex mixture, including lecithin which has been reported to comprise about 6% of the total lipid (MacMurray and Morrison 1970). Extraction of lipid from flour causes greatly increased dust levels from the flour (personal observation). This suggests that the natural flour lipids reduce dust levels from flours. However, if calcium stearate is effective at the level proposed, it might be that it would have a greater effect in reducing dust levels than that obtained by increasing the amount of one of the natural lipid components of flour.

[The Reviewer did not reply directly to questions regarding substitutes and alternative manufacturing processes]

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

It is well accepted in the industry that dust from wheat flour can present problems, particularly in smaller bakeries, and can cause allergies and asthma. This can be accentuated when certain additives such as enzymes and vitamins are added to the flour. There is thus a justification for introducing a compound to reduce the dust level from flour. Calcium stearate is being proposed for this purpose in the present petition. It is to be used at very low levels. The enrichment product in which it is incorporated contains not more than 1% calcium stearate by weight so that its concentration in flour would equate to $1/100^{th}$ of 156 ppm.

No empirical evidence that calcium stearate is effective in reducing dust from flour is provided and I am not aware of any reported in the literature. The projected use is apparently based on its use in cosmetic and pharmaceutical ingredients unless the

company has results that are proprietary. It would seem that some simple tests could measure its effectiveness. One would be measurement of the angle of repose, a standard procedure used to evaluate powders in engineering departments but there are other methods.

The incidence of asthma and allergenic reactions is increasing in the community. Anecdotal evidence suggests that it is also becoming more widespread among bakery workers. Where fortification of flour with ingredients such as enzymes and certain vitamins is made before delivery to or at bakeries, there is justification for introduction of additives that can reduce the level of dust from the flour. Calcium stearate is proposed to achieve this although no experimental supporting evidence for its effectiveness is provided in this petition. The level of addition to flour that is proposed is in the order of 150 ppm or 0.015%. Therefore, at this concentration, it will not affect the product (flour) being labeled as "organic". There is no indication of any negative effects on human health or the environment and there appear to be no reasons for not allowing it as an additive in processed products labeled as "organic" such as wheat flour.

Recommendations to the NOSB:

a) The substance should be listed as a **synthetic** on the National List.
b) The substance should be **allowed for use in for use in products labeled as "organic"** (≥95% organic ingredients).
c) The substance should be **allowed for use in for use in products labeled as "made with organic (specified ingredients or food group(s))"** (≥70% organic ingredients).

Reviewer 3 *[Organic food industry certification specialist, MS Health Education, western US]*

As a marketing program through AMS - USDA, the value of the "organic" label claim to American Farmers rests on the faith of the consumer and integrity of the word, "organic". While the word "organic" is legally defined by the USDA, it is the end consumer's expectations and confidence that should be considered in all evaluations of non-agricultural, non-organic materials. I feel morally compelled to offer this as an additional criteria for materials evaluation – I do not believe that consumers expect chemical additives, ingredients, or processing aids to be used in organic products and on this point alone I do not believe this material should be allowed in organic production systems. With that said, here is my response to the technical criteria.

NOSB Processing Criteria Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes*
   The first part of that sentence, "the substance cannot be produced from a natural source" is borne out in the materials provided by the petitioner as well a by a general search about the material. Calcium Stearate is synthesized in a dry fusion process and does not occur in nature.

   The second part of the sentence, "…and there are no organic substitutes", is less cut and dry. This material appears to be used in everything from mascara to plastics to bread. First of all, we need to examine the stated need by the petitioner: in item number 12 of the petition, they discuss why the material is needed in organic production. The need is stated as a flow agent and anti-caking agent to facilitate the use of enzymes and vitamins in baked goods while protecting the workers who make the product. This presumes that organic consumers want baked goods fortified with enzymes and vitamins. To examine this premise, I went to 3 stores in [a West Coast city] (Safeway, United Market, and Whole Foods) and examined the ingredient panels of breads and cookies and crackers. Those products labeled "organic" consistently contained only basic ingredients, wheat flour, oil, salt, some sort of leavening and, in some cases, sweeteners. The "made with organic" category currently allows the use of most processing aids, perhaps that is sufficient. Finally, the conventional baked goods consistently contained lengthy ingredient list showing dough conditioners, etc. This ingredient difference, although not hard science, made the difference between the two categories of food fairly obvious. Further, the issue of substitutes is open to all classes of materials that act as anti-caking and / or flow agents. These include maltodextrin, which is available in an organically certified version, as well as various silicates. This leads to the conclusion that there are organic substitutes for the petitioned material.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA*
   The manufacturer of the particular brand used by the petitioner refused to fully explain their manufacturing technique. This excludes a conclusion on the above criteria.

3. *The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations*
   The material reviewed in the petition and provided by the review agent, do not indicate any problems with the use of this material with reference to criteria 3.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law*
   This statement appears to be true. Calcium stearate is consistently referred to as used for mechanical aspects of processing; lubrication, release agents, flow agents, etc.

5. *It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
   Calcium stearate is listed as a GRAS material.

[In Criterion 6, the Reviewer chose to address both the criteria set forth under the Final Rule (§205.600) and under Section 2119 of the OFPA (7 U.S.C. 6518 (m)(1-7).

6. *The substance is (a) essential for the handling of organically produced agricultural products (regulatory language) or is it (b) compatible (NOSB language) with organic handling practices.*
   (a) "Essentialness", as a criteria, is a matter of interpretation. In "100% organic" or "organic" (95%) labeled products, calcium stearate is not "essential" – baked goods can be manufactured without this processing aid. The petitioner provides bakery ingredients (dough conditioners); in a casual (though focused) visit to 3 stores in [Northern California], all of which carried "organic" baked goods, I observed no currently labeled products that contained enzymes or vitamins, so I will presume that there were no other conditioning agents in the bread – none appeared on the ingredient panels. I examined approximately eight (8) different brands and fifteen (15) different "organic" products.
   (b) "Compatibility" is a similar interpretive issue. In the most conservative view, no synthetic is "compatible" with organic handling practices. In the more moderate views, it may be. Again, I return to the expectation of the consumer – do they expect "organic" manufacturer's to use synthetic ingredients or processing aids? I don't believe they do. I do not believe this material is "compatible" with organic handling practices.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process*
   It is clear that there are both mechanical and material methods to achieve the controls desired by the petitioner. While there may well be a mechanical limitation on the petitioner due to the engineering of their plant, they may be able to adapt some type of cyclone process (or even more efficient dust masks) that allows them to control dust. Additionally, there is a clear need to explore other currently allowed materials to achieve the same end. It is a human tendency to depend on familiar processes. The nature of organic production thrives on creative problem solving.

Do you have any additional references to provide?
Due to the paucity of published information focusing on calcium stearate, I spoke with two (2) food technologists and one (1) environmental chemist. The chemist works for a company that produces bakery mixes and manufacturers and uses ingredients similar to those produced by the petitioner. All of the people consulted had similar reactions; calcium stearate is ubiquitous and benign in their experience. It has been in use for so long that they are very comfortable with it.

There seems to be very little information regarding calcium stearate in food processing. Besides the Petitioner's stated intended use, in what other ways might the substance be used? Are there methods of potential use that are not compatible with the principles of organic handling?
Calcium stearate is ubiquitous in processing – for food, cosmetics, and plastics. It has also been used in packaging. It truly does not appear to have adverse effects, however the issue of labeling to the organic consumer is of concern. Not only is it a synthetic but it is also derived from animal by products. This is a separate labeling issue, although one that effects retailers.

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.
My conclusions about calcium stearate include that it is a synthetic material that should remain prohibited in the manufacture of "organic" and "100% organic" products. I would support its use in "made with organic" products provided that its use and its potential animal source are stated on the label.

Recommendations to the NOSB:
b) The substance should be listed as a **synthetic** on the National List
d) The substance should be **prohibited for use in for use in products labeled as "organic"** (≥95% organic ingredients).
e) The substance should be **allowed for use in products labeled as "made with organic (specified ingredients or food group(s))"** (≥70% organic ingredients)**, provided that its use and its animal source are stated on the label.**

* * *

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